IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **Wave 4 Cases**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

Expert Report of Harvey Winkler, MD
Regarding TVT and TVT Exact

Qualifications: Background and Education:

I am currently the Co-Chief of Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at the Northwell Health System in Long Island, New York and an Associate Professor at the Hofstra Northwell School of Medicine. I am also the Program Director of the fellowship training program in FPMRS at the Hofstra Northwell School of Medicine. Board certified in Obstetrics and Gynecology and Female Pelvic Medicine and Reconstructive Surgery by the American Board of Obstetrics and Gynecology, I am licensed to practice medicine in the State of New York. Additionally, I have an Illinois license (inactive, as I currently do not practice in that state). Pending approval, I will have an Australian medical license to consult and instruct physicians on surgical procedures, internationally.

I began medical school in 1988, at the age of 20, and graduated from the Albert Einstein College of Medicine in 1992. After which I started my residency in Obstetrics and Gynecology at Montefiore Medical Center under the auspices of the Albert Einstein College of Medicine, from July 1992 to June 1996. In July of 1996 I began my fellowship in Urogynecology under the tutelage of Dr. Peter Sand, an internationally renowned Urogynecologist, at Evanston Hospital, which was then affiliated with Northwestern University. I completed the fellowship in June, 1998. In July 1998, I launched the Urogynecology Division at Maimonides Medical Center and was appointed the Chief of the Division where I developed the division into a local center of excellence.

In May of 2002, I resigned from Maimonides and moved to North Shore LIJ which is now known as Northwell Health. In 2006 I was appointed the Co-Chief of the Division of Urogynecology: Female Pelvic Medicine and Reconstructive Surgery. In July of 2008 the Fellowship program, which I pioneered and assembled, in Female Pelvic Medicine & Reconstructive Surgery commenced and I was appointed the Program Director. I was responsible for attaining credentialing for the program and received such from the American Board of Obstetrics and Gynecology (ABOG) in 2011 and from the Accreditation Council of Graduate Medical Education (ACGME) in January 2013 retroactive to July 2012. The Fellowship program in FPMRS at the Hofstra Northwell School of Medicine is one of only 50 programs in the country currently approved by the ACGME.

I am currently a member of the American Urogynecologic Society (AUGS), International Urogynecological Association (IUGA), American College of Obstetricians and Gynecologists (ACOG), New York Obstetrical Society, (NYOB), American Association of Gynecological Laparoscopists (AAGL), and the American Institute of Minimally Invasive Surgery, (AIMIS). I have previously served as a member of the AUGS Public Relations Committee.

Throughout my career, I have championed the education of residents and fellows, training them to be future caretakers, pioneers, and leaders in women's health. I am responsible for the

resident education curriculum and rotations in Urogynecology at North Shore University Hospital and Long Island Jewish Medical Center. In June of 2012 I was awarded the APGO Excellence in Teaching Award for resident education. As Program Director for the Fellowship Program in FPMRS I am responsible for ensuring that the fellows receive a superior education, which includes but is not limited to: organizing the didactic lecture series, presenting lectures, journal clubs, morbidity and mortality conferences, and one-on-one surgical training of multiple urogynecologic procedures. Furthering my role in graduate education, I am a member of the Faculty Council of the Hofstra Northwell Scholl of Medicine as well as member of the Northwell Health Graduate Education committee.

I have also trained physicians on the techniques, patient selection, risks and complications of midurethral slings. I have travelled nationally to educate these physicians and am scheduled to do such internationally in Australia in March 2017. Furthermore, I have been invited to lecture at the Urogynecological Society of Australia annual meeting in Melbourne in March of this year.

As part of my dedication to education and requisite for continuous learning for myself in all aspects of health care, I am currently enrolled in an MBA program focusing on Health Services Management at the Frank. G. Zarb School of Business at Hofstra University. I am planning to complete the program in 3 years despite working full time, and currently have a GPA of 4.0.

Throughout my career, I have always championed women's health through knowledge, research and innovation, with the goal of quality of life improvement. These projects include my current role as Assistant Investigator in Patient Oriented Research at the Feinstein Institute for Medical Research of Northwell Health. I have been involved in numerous research projects and studies on pelvic organ prolapse and urinary incontinence. I have presented numerous abstracts and published peer reviewed articles on pubovaginal slings and synthetic midurethral slings. I have authored two chapters on female pelvic surgery in textbooks. Furthermore, I am currently the Principal Investigator developing a rabbit model for the evaluation of polypropylene and absorbable meshes.

Not only have I personally contributed to the literature for the treatment of stress urinary incontinence, but I also have been involved in evaluating the quality and content of research presented at meetings and published in journals. I have been a reviewer for the International Urogynecology Journal, Female Pelvic Medicine and Reconstructive Surgery, American Journal of Obstetrics and Gynecology and was an abstract reviewer for the AUGS 2015 Annual Meeting. My Curriculum Vitae is attached as Exhibit 1.

Clinical Experience:

Throughout my career I have been trained to perform diverse and manifold gynecologic surgeries via the open abdominal route and laparoscopically, including robotic assisted and vaginal procedures. I have performed pelvic reconstructive procedures with a patient's own tissue (native tissue repairs), cadaveric tissue, animal tissue, and synthetic materials.

During my residency I received comprehensive training in general gynecology and obstetrics. I obtained extensive training in repairing complex tears and lacerations that occur during vaginal delivery, and repaired hundreds of episiotomies. I was taught how to manage short and long term complications from episiotomy repairs and damage to the vagina and pelvic floor. During residency I learned the principals of gynecologic surgery, abdominal and vaginal, as well as indications and complications for the various gynecologic surgical procedures.

After I completed residency in 1996 in order to advance my surgical skills, as well as to perform meaningful care and research, I opted to do a fellowship (additional training) and specialize in Urogynecology, Female Pelvic Medicine and Reconstructive surgery (FPMRS). Back in 1996, Urogynecology was a field in its infancy. There were no structured, organized programs with requirements mandated by an accrediting body. Furthermore, there was no official subspecialty of FPMRS, yet, but the fellowship programs resembled apprenticeships.

During my fellowship I studied under Dr. Peter Sand, who was one of the early pioneers of Urogynecology. Throughout fellowship I learned the principals of pelvic organ prolapse (POP) and stress urinary incontinence as well as surgical and non-surgical treatment options. First and foremost, with regards to surgical management, I was trained on the anatomy and proper dissection. Once this achieved, performing procedures and learning new ones becomes commonplace. To this end, I participated in numerous cadaver labs, attended conferences, and received one-on-one surgical training in the operating room.

My education and training in fellowship for pelvic organ prolapse focused on vaginal native tissue repairs performing vaginal hysterectomy, sacrospinous suspensions and uterosacral suspensions for apical vaginal prolapse and colporrhaphy for cystocele and rectoceles. During fellowship I did not perform an abundance of abdominal prolapse repairs. When I completed fellowship I was an expert vaginal reconstructive surgeon but I subsequently learned and became an expert abdominal and robotic surgeon through hard work and dedication.

During fellowship, I received additional training in caring for women with complex pelvic floor disorders including managing and treating the complications that can arise from these procedures. Specifically in regards to stress urinary incontinence procedures, I learned how to perform abdominal retropubic colposuspensions including the Burch procedure, MMK, and paravaginal repairs. The primary retropubic colposuspension for SUI that I have performed was the Burch procedure. However, the frequency that I perform a Burch today has significantly decreased due to the success of the midurethral sling.

In the late 1990's, needle procedures were still being performed and I had the opportunity to learn and perform these procedures as well, during fellowship, including the RAZ and Vessica procedure. Neither of which are performed today due to their poor efficacy. However learning these procedures, specifically the Vessica procedure, facilitated my education and adoption of the TVT procedure.

During fellowship I also received extensive training and performed various types of pubovaginal slings including: rectus fascia, Gore-Tex, bone anchored slings, vaginal patch slings, cadaveric and the ill-fated Protegen (braided polyester) sling.

During my training and throughout my career I learned the risks and benefits of the various surgical procedures as well the appropriate candidates for them. As a surgeon treating women with stress urinary incontinence, it is not only important to learn how to perform the procedures, but one must become knowledgeable and become competent in managing the inevitable inherent common and unique complications. To this end, I learned how to perform removal or revision of synthetic materials, removal of scar tissue, fistula repair, urethrolyisis for persistent voiding dysfunction or urinary retention, and medical and surgical management for chronic pain or dyspareunia. To this day, I continuously learn about surgical complications and management of such through reading the literature and attending conferences. As a result, physicians across the region refer to me complicated patients and patients suffering from surgical complications.

I previously mentioned that during my fellowship I only performed few abdominal procedures for POP. Additionally, during the time period of my formal training robotic surgery did not exist, nor did the tension free mid-urethral sling exist. In order to learn these procedures I went to additional courses, as well as operated with surgeons who were skilled in these procedures. Subsequently, I became an expert in both abdominal as well vaginal POP procedures as well as surgical management for SUI. I developed the ability to provide the appropriate surgical procedure for the patient rather then find the suitable patient for the surgical procedure I performed. This ability allowed me to become a true expert in the field of FPMRS.

As stated above, midurethral slings were not available in the United States during the time of my fellowship which necessitated learning the procedure after my official training was completed. Learning the procedure for me was not difficult due to my previous extensive training and exposure to pubovaginal slings and needle procedures. Early in 1999, I observed and attending a didactic teaching session with Dr. Vincent Lucente in Allentown, Pennsylvania. After observing

the TVT procedure and reading the literature that was available at the time, I felt comfortable offering the procedure to patients and performing it.

Throughout my career not only have I been a continuous learner but a teacher as well. I have taught residents, fellows, and practicing physicians. To this end, I have given didactic lectures on the evaluation and surgical treatment of stress urinary incontinence including managing complications from the procedures. As an expert in the field, through our fellowship program, I have been given the responsibility of training the future subspecialists and experts in Female Pelvic Medicine and Reconstructive Surgery.

The reality that I needed to learn surgical procedures after my official training period has driven me to provide this opportunity to other physicians who wish to expand their surgical armamentarium and provide the highest quality of care to the women they treat. I have taught training sessions, didactic, and cadaver labs over the past several years to hundreds of urologists, gynecologists, and FPMRS physicians. I have also have had physicians observe surgical procedures that I perform. Continuous life learning is one of the core competencies that is mandated by the Accreditation Council for Graduate Medical Education. Learning, advancing, and fine tuning surgical knowledge and skills are undoubtedly invaluable and these labs provide that opportunity. I myself learn something new at each one of these teaching opportunities. Similarly, surgeons are expected to stay current with the medical literature in their field, and especially for the procedures they are performing.

During my career, I have performed approximately 250 robotic sacral colpopexies, 500 open sacral colpopexies, 1000 uterosacral and high uterosacral suspensions, 300 sacrospinous suspensions, 200 transvaginal mesh procedures, 600 Burch procedures, 200 autologous fascial slings, and 3000 midurethral slings including retropubic, transobturator, and single incision slings. I have implanted traditional TVT, mechanically cut and laser cut, and have not noticed a difference in complications. I currently use TVT exact as one of the retropubic midurethral slings that I implant.

I have had extensive experience in treating complications after gynecologic surgeries, including after Burch, needles procedures, autologous, and midurethral sling procedures. My first exposure to surgical complications occurred in medical school typically from rotations on the surgical and obstetrics and gynecology services. The majority of the complications observed were a result of everyday surgical procedures performed. I learned early in my career that complications can occur from the most minor procedures and the majority of complications materialize after routine surgical procedures. The adage of the definition of "minor surgery is surgery performed on someone else" was ingrained in me when I was only a medical student.

I received further training in preventing, identifying and treating surgical complications during residency. I learned to evaluate and manage intraoperative and short and long term complications of open abdominal, laparoscopic and vaginal surgery through didactic lectures, reading textbooks and journal articles as well as one-on-one training with attending surgeons.

The bulk of my training in dealing with surgical procedures has come from my fellowship training and continuing medical education as a practicing physician. During fellowship and practice I have obtained extensive knowledge and skills in managing complications after Burch procedures including: bleeding, infection, injury to the bladder, injury to blood vessels and nerves, urinary retention and voiding dysfunction, urgency, frequency, urge incontinence, pelvic pain, dyspareunia, enterocele and pelvic organ prolapse, suture erosion into the bladder, and fistula. I have also obtained extensive knowledge and skills in managing complications from synthetic and autologous pubovaginal slings including, retention, voiding dysfunction, erosion, fistula, urgency and urge incontinence, dyspareunia, and pelvic pain. As a practicing surgeon I have also managed complications from midurethral slings including: retention, voiding dysfunction, exposure/erosion into the vagina, urethra and bladder, urgency incontinence, fistula, dyspareunia, and pelvic pain.

Materials Reviewed:

Throughout my career I have extensively researched, reviewed and contributed to the published medical literature describing the safety and efficacy of stress urinary incontinence treatments and procedures, including slings and midurethral slings.

In preparing this report I have searched and reviewed hundreds of medical and scientific literature regarding the design properties of meshes and the safety of TVT. In addition to reviewing the materials provided to me, I have performed literature searches in response to the claims that TVT is not reasonably safe for the treatment of stress urinary incontinence. Most of the articles I have reviewed in preparation of this report I had already reviewed as part of my due diligence and continuing medical education throughout my career.

I have reviewed the TVT Instructions for Use, Patient Brochures, and Professional Education materials. A complete set of the materials I reviewed are set forth in my reliance list, attached to my report as Exhibit 2. I reserve the right to supplement my report based on my review of new materials. Additionally, I have reviewed plaintiffs' experts' general reports and the literature and documents they cite in their reports to support their opinions.

Expert Testimony:

Granados, Bethany an infant by Nora v. Moon (2013)

Fees:

My expert fees in this matter are as follows: $650/hour for reviewing cases, working on reports, and meetings; $ 7,000/day for deposition testimony; and $8,000/day for trial testimony.

Opinions:

Stress urinary incontinence (SUI) significantly affects women's quality of life

Stress urinary incontinence (SUI) is the involuntary loss of urine during effort or exertion, or on sneezing or coughing. It occurs when intra-abdominal pressure increases the bladder pressure enough to exceed the urethral pressure in the absence of a detrusor contraction. It may occur during common daily activities such as exercising, running, and laughing or during sexual intercourse. Risk factors for developing stress incontinence include age, parity, and obesity. SUI is estimated to affect 12-46%[1] of all women and 15.7% will have moderate to severe leakage and therefore are more likely to pursue treatment[2]. Unfortunately a large percentage (63.5%) of women with stress incontinence experience loss of urine during sex[3]. It is estimated that 13.6 % of women will undergo at least one surgery for stress urinary incontinence in the US[4].

Numerous validated questionnaires have been developed measuring quality of life in women with urinary incontinence including the IIQ-7 which measures the impact of urinary incontinence on various activities, roles, and emotional states, UDI-6 which measures the bothersomeness of urinary incontinence symptoms, and the PISQ which measures sexual function in women with urinary incontinence or pelvic organ prolapse. SUI negatively impacts women's confidence, personality, self-perception, social activities, daily activities and physical activities[5]. SUI causes a psychosocial impact, social embarrassment, and results in avoidance and limiting behavior. SUI limits the activities women engage in and urinary incontinence has been shown to be perceived obstacle to exercise[6]. SUI has been shown to adversely affect sexual function[7]. Lower quality of life scores are associated with more SUI symptoms, SUI in younger women and with greater symptom bother[8].

Non-surgical treatments for SUI

Treatment options for SUI include no treatment, behavioral modification, pelvic floor muscle training (PFMT), intravaginal devices, medications, bulking agents and surgery. Behavioral modification includes fluid management, bladder training and weight loss. Obesity is a risk factor for developing SUI and weight loss has been shown to improve the symptoms of stress

incontinence in this patient group. Behavioral modification options typically require continued control and management.

Pelvic floor muscle training has been shown to improve SUI although total cure and dryness rates are low[9]. In a study comparing PFMT to surgery with a midurethral sling, 49% of patients randomized to PFMT crossed over and proceeded to have surgery for their SUI. Women with moderate to severe incontinence had significantly better subjective and objective cure rates with surgery[10]. In the ATLAS trial, an RCT of nonsurgical treatment for SUI, 43% of women stopped performing pelvic floor muscle exercises by one year[11].

Intravaginal devices such as pessaries and over the counter mechanical options to support the urethra and treat stress incontinence are available. In the ATLAS trial, 26% of patients randomized to a pessary dropped out by 3 months and 55% stopped using the pessary by 12 months[11]. A recent Cochrane review on mechanical devices for SUI concluded that the current evidence is inconclusive on their value in treating SUI[12]. An approved over the counter device was not included in this review but it can only be worn for 8 hours daily and adverse events include discomfort, pain and vaginal spotting. In my experience, clinically, patients do not opt for intravaginal devices as a practical long term treatment option as they are cumbersome and inconvenient.

In the US, there are currently no approved drugs for the treatment of SUI. Tofranil an "old" type of antidepressant medication can been used off label by clinicians. Common side effects of Tofranil include: dry mouth, blurred vision, headache, drowsiness, dizziness, and constipation. Published data of the efficacy of Tofranil is scarce and no randomized trials exist for its use in the treatment of SUI. Tofranil must be taken continuously to be efficacious, this combined with the side effect profile do not make it a popular treatment preference for SUI in women. The ACOG and AUGS practice bulletin on urinary incontinence states "medical therapies for treatment of stress urinary incontinence are less effective and generally are not recommended"[13].

A relatively noninvasive treatment for SUI is injecting bulking agents such as pyrolytic carbon-coated beads, polydimethylsiloxane, and calcium hydroxylapatite into the urethra at the level of

the bladder neck and midurethral under cystoscopic guidance. Transurethral bulking can commonly be performed as an office procedure. Urethral bulking does not have a long lasting effect thus requiring repeat injections, and it less effective than surgical correction. A Cochrane review on bulking agents concluded that there was limited evidence that bulking agents can effectively treat SUI. Surgical management has1.7 to 4.8-fold increased likelihood of curing SUI as compared to bulking agents[14].

Nonsurgical treatment options offer patient methods to functionally control SUI and these management techniques must be performed on a daily and/or continuous basis. In essence, they are not curing SUI but converting it into a chronic condition. Conversely, surgical treatment for SUI offers women the option of a long lasting cure. To this end, the ACOG practice bulletin states, "initial midurethral sling surgery may be offered as an alternative primary treatment option in appropriately counseled women"[13].

Historical surgical treatments for SUI

Prior to the introduction of midurethral slings in the late 1990's patients who opted on surgical correction for their stress urinary incontinence had to either endure invasive procedures with acceptable success rates or less invasive methods with poor success rates. These procedures included: anterior vaginal repair, needle suspensions, MMK, Burch, autologous fascial slings, and synthetic pubovaginal slings. By 1998 there were more than 100 surgical procedures described to correct SUI. Unfortunately many of these procedures did not have reproducible outcomes, were difficult to teach, and had a high complication rates.

In the early 1990s, gynecologists, more commonly, were performing vaginal procedures such as anterior repair/Kelly plication. Kelly first described suturing the tissue under the bladder neck as a treatment for stress incontinence in 1914, and 80 years later gynecologists were still performing the procedure despite poor short and long term longevity. Failure rates at one year were 29% subjectively[15] and 63% objectively at five years[16].

During the same time period urologists were generally performing needle procedures, including the Pereyra (described in 1959), Stamey, and Raz, as well as numerous modifications of each. Long needles, similar to the TVT trocars, are used to pass suture from the anterior abdominal fascia to the vagina. These sutures are stitched to the vaginal tissue next to the bladder neck on both sides in an attempt to support the bladder neck and treat SUI. The subjective failure rate at 1 year was 29%[17] and objectively at five years was 57%[4]. Besides the high failure rate, common risks of needle procedures include bowel and bladder perforation. Needle procedures and Kelly plication for the treatment of SUI have consequently been long abandoned by surgeons due to their poor success rates. In fact, the National Institute for Health and Care Excellence (NICE) noted in its 2006 and 2013 Urinary Incontinence Clinical Guideline: "Do not offer anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall-Marchetti-Krantz procedure for the treatment of stress UI."[18]

Retropubic colposuspension, such as the MMK and Burch, are abdominal procedures which are often performed using an open Pfannenstiel incision similar to a cesarean section or hysterectomy incision or less frequently laparoscopically. Both procedures suspend the bladder neck, the MMK to the symphysis pubis and the Burch to ligaments on the pelvic sidewall. Retropubic colposuspension has been shown to have good success rates of 85-90% at one year and approximately 70% after 5 years[19]. In addition to the usual complications of open abdominal surgery the MMK has a unique post-operative complication of osteitis pubis, debilitating pain and discomfort over the pubic symphysis, occurring in 2.5% of women[20]. As a result the Burch procedure was preferentially performed.

Long term voiding difficulties have been reported to be a major concern after Burch colposuspension occurring in 22-32% of patients[21]. Kholhede et al (2005) reported on 14 year follow-up after the Burch with a 44% cure rate and only 19% considered themselves completely cured with no incontinence episodes. Kholhede reported de novo urge symptoms in 36% of patients, as well as recurrent UTIs in 16% and 10% at 6 and 14 year follow-up (compared to Lose reporting 29% UTI at mean follow-up of 26 months and Alcalay reporting 5% recurrent UTIs, 15% de novo detrusor instability, and 22% long-term voiding difficulty at 10-20 year

follow-up). At 14 year follow-up, 43% of incontinent women and exhibited at least one of the symptoms of voiding problems. While the authors noted the historical effectiveness of the Burch, they also discussed how it is "encumbered with a significant post-operative morbidity, such as increased occurrence of voiding difficulties and genital prolapse." They also noted the long-term results with Burch cure rates decrease with time.

Eriksen et al (1990) reported a 67% cure rate, with only 52% cured and complication-free at 5 year follow-up after Burch. Complications at 5 year follow-up included: 30% needing further incontinence therapy; late voiding difficulties were observed in 3%, enterocele occurred in 10% with 7% requiring surgical correction; 3 patients developed persistent fistula to prosthesis; dyspareunia; 3 patients suffered from recurrent cystitis; 34.9% had post-void fullness; 34.9% had stranguria; 33.7% had urgency; 16.3% had frequency; 24.4% had nocturia; 15.1% had urge incontinence; 19.8% had mixed incontinence; 12.8% had stress incontinence; one patient had a kidney that was damaged due to a complete ureteral obstruction; 8.1% had cysto-urethrocele; 17.4% had a rectocele; 14% had an enterocele.[22]

Christensen et al (1997) reported on complications after Burch at median 7 year follow-up and found that only 41.9% of patients were very satisfied with the procedure, while 37.2 were dissatisfied[23]. Complications in the Burch group occurred in 23% of patients and included: wound infection, DVT, chronic urinary retention, new onset urgency, suture erosion to bladder, 28.6% of patients requiring a reoperation, including suture removed from the bladder. The authors noted that "chronic urinary retention and new onset urgency are well-known complications after incontinence surgery."

Stanton et al (1995) reported on complications associated with MMK, Burch, and slings, noting that the most important complication following an MMK procedure is osteitis pubis found in 5-10% of patients, while also noting common post-operative complications Burch colposuspension to include voiding difficulty, detrusor instability at 5-10%, recurrence of incontinence, and dyspareunia. Stanton noted that if dyspareunia persists in patients after Burch colposuspension,

it may be attributable to a prominent posterior vaginal wall ridge or a change in anatomic axis of the vagina.[24] With respect to slings, Stanton noted the common complications as being voiding dysfunction, exposure or erosion of the sling, and detrusor instability. He also discussed how the potential complication of "erosion through the anterior vaginal wall and erosion into the urethra or bladder are known complications."

The laparoscopic Burch limits the incisional complications as compared to an open procedure. However the laparoscopic approach is associated with a higher risk of vascular and bowel injury as well as a higher cystotomy rate than the open procedure[25]. The required extensive experience in laparoscopic surgery and the long operative times of a laparoscopic Burch have limited its acceptance and capacity to be an advantageous, widespread, alternative treatment. In addition to the operative risk of retropubic colposuspension, there is also an increased risk of developing pelvic organ prolapse from the procedure[26] and the need for further surgical intervention. The NICE Clinical Guideline, previously noted, recommends that surgeons should not offer laparoscopic colposuspension as a routine procedure for the treatment of SUI in women.

Traditional or autologous fascial slings have been associated with slightly higher success rates then retropubic colposuspension, albeit with higher post-operative complication rates[27]. Autologous slings require the harvesting a strip of tissue from the patient, usually from the abdomen (rectus fascia) or thigh (fascia lata), and then using an abdominal and vaginal approach to place the strip of tissue under the bladder neck. Harvesting a strip of fascia lata requires an additional incision on the thigh. Autologous slings, compared to the Burch, have increased risk of postoperative voiding dysfunction and catheterization rates. Despite these risks in the late 1990's, surgeons, predominantly urologists were advocating pubovaginal slings as a primary procedure for stress urinary incontinence[28]. By 1999, the pubovaginal sling was the most commonly recommended surgical procedure performed by urologists for SUI[29]. Conversely, gynecologists were more commonly performing an open Burch procedure.

In the mid to late 1990's, in order to decrease the operative time and morbidity of traditional pubovaginal slings, surgeons used various biologic and synthetic materials, as well as novel anchoring techniques, without much clinical data to surgically treat stress urinary incontinence. Surgeons began using bone anchors placed into the pubic bone to anchor the sling with sutures thereby avoiding large or any abdominal incision. Once again these procedures met with poor success rates as well as the added morbidity of pubic osetomyletis. Carbone et al (2001) reported their experience with a bone anchored slings. Within one year 37.6% had recurrent stress urinary incontinence and the reoperation rate was 16.9%[30].

In 1997 Leach performed a meta-analysis for the American Urological Association (AUA) and concluded that retropubic suspensions and slings were the most efficacious treatments for SUI[31]. Procedures that had higher and acceptable success rates such as the Burch, MMK and autologous fascial slings were invasive, had long operative times, necessitated large incisions, and had increased risk of surgical and postoperative complications, prolonged hospitalization, catheterization, and recovery. These procedures are also associated with increased risk of bleeding, pain, wound infections, and DVT. Marinkovic et al (1998) reported a 42% complication rate with a Burch and 26% with a pubovaginal sling[32]. Additionally, these procedures involved a high amount of skill and were difficult to standardize and teach. As a result, locating an experienced surgeon who performed these procedures was challenging. This combined with the invasiveness of the "old" procedures dissuaded women to proceed with definitive management. As a result they unfortunately suffered and endured their symptoms of stress urinary incontinence. There was a necessity for a superior and simpler procedure which was achieved with the introduction of the TVT procedure.

The AUA's updated 2012 Guideline for the Surgical Management of Female Stress Urinary Incontinence reports the following complications for autologous fascial slings: pain 10%, sexual dysfunction 8%, and voiding dysfunction (only case reports of this complication exist, and data are insufficient to estimate the frequency)[33]. The same panel reported the following complications for Burch colposuspension: pain 6%, sexual dysfunction 3%, and voiding

dysfunction 10%. For synthetic midurethral slings, subjective complications included: pain 1%, sexual dysfunction 0%, and voiding dysfunction 2%.

Evolution of synthetic materials for treatment of SUI

In order to reduce operative time, standardize and simplify the procedure, avoid large or additional incisions, reduce pain, reduce the possibility of hernia development, and to use a material that is more consistent and possibly stronger than a patient's own tissue surgeons began utilizing various synthetic materials in incontinence repairs[34].

Complications from various synthetic mesh repairs were well-documented in the literature prior to the introduction of the TVT. Surgeons in the 1960's were already using a synthetic material for pubovaginal slings. Telinde (1961)[35], Moir (1968)[36], and Nichols (1972)[37] reported their results using a Merseline, polyethylene or polyester, mesh. Complications described included suprapubic abscess, voiding dysfunction, exposure, and the possibility of bowel injury were documented at the time. Kersey (1983) published results on 105 women who underwent a Merseline pubovaginal sling[38]. Two patients developed vesico-vaginal fistula and 3 patients developed mesh exposure. Young et al (1995) reported their results using a Merseline sling on 110 women, mean follow up was 16 months and mean operative time was 134 minutes, which is considerably longer than the TVT sling procedure performed today. Mean time of postoperative catheterization was 10 days, exposure occurred in 0.9% of women and 2.7% had long term inadequate voiding[39].

Ostergard (1996) published a retrospective study on patients who underwent a Teflon sling and the risk of developing permanent voiding dysfunction postoperatively. The mean duration of post-op catheterization was 10.7 weeks, and 22% complained of voiding difficulty one year or more after surgery[40]. In the same cohort of patients, 40% developed wound complications and 22% needed to have the sling removed[41].

Physicians were also using Gore-Tex as a sling material in the 1990's and they published numerous complications associated with it use. Bent (1993) reported a 20% removal rate for a full Gore-Tex sling[42]. Norris (1996) published retrospective data on 122 patients with a mean follow up who received a Gore-Tex patch sling for SUI. Sling exposure requiring removal occurred in 4% of women, 5% had the sling incised for urinary retention or severe voiding dysfunction and 32% developed de novo detrusor instability. A discussion of complications from early synthetic sling studies can be found in Iglesia 1997[43].

Table 2A. Suburethral sling with Marlex mesh: surgical outcome [17–20,63]

Author	No. pts	Follow-up	Cure rate SUI*	Mesh-related complications
Morgan 1970	20	3–23 mos	100% subjective	1 obstruction; 1 VVF‡
Bryans 1979	69	5–8 yrs	79% subjective	22% voiding dysfunction 5 poor vaginal healing 2 vaginal removal 1 sinus tract
Hilton/Stanton 1983	10	3 mos	80% subjective 70% objective	not reported
Morgan 1985	284	5 yrs	77% subjective	12 urethral erosions 14 prolonged retention, with transurethral resection of bladder neck in 12
Drutz 1990	65	24 mos	95% subjective	4 poor vaginal healing with partial removal 1 transurethral resection of mesh

Table 3A. Suburethral sling with Mersilene mesh: surgical outcome [24–27,64,69,71,75]

Author	No. pts	Follow-up	Cure rate SUI*	Mesh-related complications
Williams 1962 (Mersilene ribbon)	12	Not stated	83% subjective	1 removal for suprapubic abscess
Ridley 1966 (Mersilene ribbon)	17	6 mos	94% subjective	1 bladder erosion 1 urethral erosion 1 graft infection
Nichols 1973	22	1–2 yrs	95% subjective	not reported
Kersey 1983	105	6 mos-5 yrs	84% subjective	2 VVF‡; 3 vaginal erosions with trimming
Iosif 1985	44	3–11 yrs	73% subjective 73% objective	7 sling divisions for retention 2 abscesses
Kersey 1988	100	6 mos–5 yrs	78% subjective	2 Prolene suture exposures
Guner 1994	24	24 mos	96% subjective	none reported
Young 1995	110	13 mos	95% subjective 93% objective	3 voiding dysfuncion 1 midvaginal band 2 vaginal erosions 1 groin sinus

Prior to the introduction of the TVT surgeons were also using polypropylene as a sling material. Drutz (1986)[44] and Morgan (1985)[45] published their results using a Marlex, woven polypropylene, pubovaginal sling. Hom (1998)[46] published preliminary results on 35 women

using a polypropylene mesh and bone anchors. Synthetic materials for pubovaginal slings had been used for over 35 years with known and well published complications, albeit retrospectively. Ulmsten's early studies discuss the problems he experienced with other synthetic materials, and why Prolene became his material of choice for TVT.

The primary modification and true revolutionary component of the TVT procedure was not the use of a synthetic component for a sling procedure, but rather, placing it under the midurethra. Minimizing dissection simplified and shortened the procedural time and resulted in shorter hospital stays, quicker patient-recovery times to return to normal activities, and reduced post-op voiding dysfunction and catheterization. This combined with positioning of the sling under the midurethra without tension created reducibility of the procedure with less complications and morbidity. Ulmsten's selection and clinical evaluation of Ethicon's Prolene mesh used for TVT demonstrated better tolerance and biocompatibility compared to the previously used synthetic materials. Indeed, the TVT procedure is one of the few SUI procedures that had published data prior to its worldwide introduction and adoption[47,48].

Approximately 2.5 years after the introduction of the TVT in the US, with over 100,000 TVT procedures having been performed in the early 2000's, there was already robust reassuring published data on the safety and efficacy of the procedure and additional studies were underway. Ward et al (2000) presented at the annual ICS meeting and published, in abstract form, short term 6 month RCT data on TVT vs Burch. They reported that the TVT procedure had decreased postoperative pain and shorter hospital stay. Subjective and objective cure rates were similar between the 2 groups. There was no difference in increased dyspareunia or de novo detrusor between the 2 groups[49]. The 6 month data showed that postoperative complications were more common after Burch, and that operation time, duration of hospital stay, and return to normal activity were all longer after Burch than with TVT.[50] Nilsson et al (2001) published 5 year prospective long term data, reporting an 85% objective and subjective cure rate for TVT[51]. Meschia et al (2001) prospectively reported on the safety and efficacy of the TVT procedure at a median follow-up of 21 months, with 21% having concomitant procedures. Subjectively 92% and objectively 90% of woman were cured. Two patients (0.5%) required a laparotomy for

intraoperative bleeding, 1 (0.25%) had an obturator nerve injury, 2 (0.5%) had the sling cut due to voiding difficulties and 2(0.5%) had a vaginal mesh exposure. The authors concluded "that the TVT procedure is associated with a high cure rate and low morbidity"[52]

The benefits of TVT revolutionized the treatment of SUI

The TVT procedure is a minimally invasive method associated with fewer complications than Burch and autologous sling including: lower blood loss, wound infections, operative time, faster recovery, fewer hospitalizations and hematomas. Due to the fewer complications and the minimally invasive nature of midurethral slings they are the preferable primary surgical modality to treat SUI. In terms of reoperation for urinary incontinence retropubic midurethral slings have the same, 6%, rate as Burch and pubovaginal slings[53]. As such, midurethral polypropylene slings, like TVT, are the most commonly performed incontinence procedure throughout the world and have been adopted as the treatment of choice by the leading professional societies and regulatory bodies. The 2013 NICE Guideline specifically refers to Ethicon's TVT and TVT-O for satisfying the requirement for having robust RCT evidence in the footnote to the recommendation that when offering a synthetic midurethral sling, surgeons should "use procedures and devices for which there is current high quality evidence of efficacy and safety." The NICE Guideline continues on to suggest that surgeons should only use a device that they have been trained to use, use a device manufactured from type 1 macroporous polypropylene tape, and consider using a colored tape for increased visibility.

The TVT procedure, which has been shown to be comparable in success rates to the Burch procedure, has numerous benefits to patients and society making it the preferable primary surgical treatment for the majority of women with SUI. Operative time is shorter for TVT[54]. Blood loss, analgesic use, post-operative catheterization, wound infection, and DVT are lower with the TVT[55]. Hospital stay is consistently shorter, 4 days less, among studies for TVT. In my practice patients may return to work in days and full activity, barring sexual activity, 2 weeks after the surgical date. Finally, TVT has been shown to be more cost effective than the Burch procedure[56].

The TVT procedure also has numerous advantages over autologous fascial slings. There is no need for larger or additional incisions to harvest the tissue thereby eliminating the risk of hernia occurrence, which is a unique risk of Burch and autologous fascial slings. Wiskind et al (1992) noted that postoperative genital prolapse is a significant complication of Burch colposuspension, finding that 35 patients (26.7%) required a total of 40 operations to correct genital prolapse after undergoing a Burch colposuspension.[57] They also noted that the general incidence of enterocele after the Burch procedure reported in the literature ranges from 3% to 17%. Operative time and analgesic use is significantly reduced due to not having to harvest the sling, no need for substantial abdominal incisions, and reduced vaginal dissection for TVT[58]. With TVT slings there is no risk of the inability in obtaining a suitable tissue implant. This is a benefit because the synthetic mesh which has been shown to be biocompatible and has a well-known safety profile as an implantable suture and mesh, provides more predictable and durable support. The risk of developing de novo urgency and detrusor overactivity, post-operative voiding dysfunction, and surgical release is higher with traditional procedures than with midurethral slings[22].

The majority of complications specific to a TVT procedure are easily managed. Bladder perforation at the time of surgery, a risk that is usually inconsequential as long as it is identified during the recommended cystoscopy, is simply handled by removing and repositioning the sling and possibly a few days of catheterization. Additionally, experienced surgeons have a lower rate of bladder perforation and the estimated rate of bladder perforation with a retropubic sling is 1.9%[59]. This rate compares to the 3% cystotomy rate for Burch as reported by Albo et al[60]. Vaginal perforation with a TVT requires repeat placement with no long term complications. Postoperative urinary retention is generally treated by cutting the sling with or without excision[61] and typically does not require extensive urethrolysis as pubovaginal slings do[62]. Postoperative erosion of the TVT into the bladder or urethra is rare and is reported to be 0.02%[63]. A similar rate of 0.18% suture erosion into the bladder is seen in Burch procedures[64].

The TVT procedure is sufficiently standardized rendering it relatively easy to teach and learn and has reproducible high success rates. Since the introduction of the TVT placing it under the mid-urethra, without causing the mesh to pull or band, in a tension free manor has been a pivotal component of the procedure. This was taught to me when I originally trained on TVT and I have easily taught this fundamental skill to countless residents, fellows, and practicing physicians.

However, just as every patient is slightly different, so is every surgeon as to how each would like to ensure that the sling is placed "tension free". Every individual surgeon should be able to do such, in order to provide the optimal procedure in their hands, for their patients. Additionally when placing the sling and removing the plastic sheaths, as directed in the IFU, averts the mesh from roping and curling, thereby keeping the pores open which prevents shrinkage and contraction. The early adoption and description of the TVT procedure is clearly evident by the publication of the procedure in the early 2000's in various peer-reviewed journals which further instructed surgeons on its use[65,66].

Furthermore, surgeons may clinically opt to tension the sling "looser" in certain patients as opposed to others. For instance, in patients with intrinsic sphincteric deficiency or low leak point pressures, surgeons may choose to leave less space between the tissue and the sling but still placing it in a tension-free manor. An IFU must give surgeons the ability to individualize the procedure and surgical management to each and every unique patient. Therefore, in the surgeons view an IFU is formulated as a guide in order to not constrain his or her ability to individualize care.

The TVT procedure has been shown to provide high objective and subjective, short and long term cure rates, with low complications, for stress urinary incontinence. It has improved the quality of life in countless women throughout the world. It has been evaluated and shown to be effective for stress urinary incontinence in a variety of patient populations including patients with intrinsic sphincter deficiency, mixed incontinence, recurrent incontinence, young and old patients, and patients with low and high BMI's. Despite the high success rates of the TVT, there

are failures, as with any procedure, and surgeons are acutely aware that certain types of patients may have higher success rates than others.

The TVT procedure has been shown to be effective in patients with stress incontinence and intrinsic sphincter deficiency. Bai et al (2007) published a retrospective review on TVT in patients with and without intrinsic sphincter deficiency. At 12 months there was no significant difference in subjective cure rates between the two groups[67]. Choo et al (2012) reported subjective results, at least 3 years after the procedure, in a retrospective review on TVT in patients with and without intrinsic sphincter deficiency. Mean follow up was approximately 4 years and there was no significant difference in cure rates. The subjective cure rate was 75.3% and 76.7% in in patients without and with intrinsic sphincter deficiency respectively[68].

TVT has been shown to be an effective surgical treatment in patients who failed a previous incontinence procedure. Ulrich et al (2016) reported on women who underwent a midurethral sling in patients after a failed Burch or midurethral sling. The majority of women, 89%, received a TVT as the secondary procedure. At a median of 11 years follow up, objective and subjective cure was 65 and 67% respectively, and 78% reported success based on a QOL questionnaire[69]. Pradhan et al (2013) performed a review and meta-analysis of surgical treatment of recurrent stress urinary incontinence. Subjective cure after a TVT sling for recurrent stress incontinence was 79.8% at a mean of 27 months[70].

TVT has been shown to be an effective surgical treatment in patients with mixed incontinence. Kulseng-Hansen (2007) reported on compiled data, from the Norwegian incontinence database, on results of the TVT procedure in 1,113 women with mixed incontinence at a median of 7 and 38 months follow up[71]. Stress incontinence was cured in 87.3 and 82.7% of women respectively. There was no difference in objective cure in patients who had predominant stress incontinence, predominant urge incontinence, or equal stress and urge incontinence complaints. Jain (2011) performed a systemic review and meta-analysis on the effectiveness of slings in patients with mixed urinary incontinence[72]. Cure rates for the stress incontinence component were 85-97%

and 30-85% for the urge incontinence element with rates decreasing over time for the urge component. There was no difference in cure rates in patients who underwent a TVT vs transobturator slings. Athanasiou (2013) performed a prospective study comparing TVT to TVT-O in patients with stress incontinence and urodynamic detrusor overactivity who failed conservative management[73]. At 12 months there was symptomatic improvement in frequency, urgency, urge incontinence, and stress incontinence with no significant differences between the two groups. At 12 months 85% of the women in the TVT group had negative urodynamic findings for stress incontinence and 48.5% had no evidence of postoperative detrusor overactivity.

Midurethral slings have been shown to beneficial and efficacious in overweight and obese women. Killingsworth et al (2009) retrospectively reported outcomes at one year in normal, overweight, and obese women who underwent a TVT sling. There was significant improvement in UDI-6 and IIQ-7 scores and high patient satisfaction in all 3 groups with no difference in complications or improvement rates between the 3 groups[74]. Xia et al (2016) recently performed a meta-analysis to determine if obesity is a risk factor for a midurethral sling. They reported that subjective success rates were similar in obese, overweight and normal weight women. Although the objective success rate was lower in overweight and obese patients, this finding is likely clinically meaningless. There was no difference in complication rates between normal, overweight or obese patients in most studies[75]. Before the introduction of the midurethral sling many surgeons opted not to surgically treat obese or even overweight women, with a Burch procedure or a pubovaginal sling simply due to their weight increasing the morbidity and technical difficulties in performing the procedures. With the advent of the midurethral sling, these patients now had a viable and safe surgical treatment to opt for.

TVT has been shown to improve the quality of life in women. The TOMUS trial compared TVT to TVT-O and TOT slings in a RCT. One year after surgery 90% of women who received a TVT conveyed a high level of satisfaction with respect to: urine leakage, urgency to urinate, frequency of urination, capability of physical activity, social activity, ability to engage in sexual activity,

and from an emotional standpoint[76]. Furthermore 95% would have the procedure again and recommend it to friend or family member.

Quality of life improvements are seen in women over 70 years of age as well as younger than 70. Koops (2006) reported prospectively on women who received a TVT 2 years after surgery. There was significant improvement in the Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6) and there was no difference seen in older vs younger women[77].

The TVT procedure has been shown to be effective in patients who had previous incontinence or prolapse surgery. Koops et al (2006) reported significant improvement in IIQ-7 and UDI-6 scores in patients with previous surgery and they did not significantly differ from patients who did not have prior surgery[78].

TVT slings have been shown to improve incontinence during sex in patients with SUI. Lindquist et al (2016) reported prospective sexual function short (6 months) and long term (57 months) after a TVT. At both time points there were improvement in sexual function QOL questionnaires. There was significant decrease in coital incontinence and fear of being incontinent at both time points[79].

The midurethral sling has also become the preferred method of secondary surgical management in patients who have failed a midurethral sling. Hansen et al (2016) reported from the Danish National Registry that 45.5% of women had a repeat midurethral sling for recurrent stress incontinence and only 2.8% underwent a pubovaginal sling and 1% Burch colposuspension[80].

The design of TVT is state of the art and is reasonably safe for its intended use in treating stress urinary incontinence. This is supported by my clinical experience and hundreds of clinical studies, including numerous systematic reviews, meta-analyses, and RCTs evaluating the safety and efficacy of TVT.

Amid (1996) defined 4 distinct mesh groups; Type I - Macroporous >75 μm, Type II – Microporous < 10μm, Type III - Macroporous with microporous component, and Type IV - submicronic pores[81]. Seventy-five microns is the required pore size for fibroblasts, collagen fibers, blood vessels and importantly macrophages, which help fend off infection, to enter. Pore size is integral on how a mesh performs when implanted in the body. While some authors have suggested that a pore size of 1mm or greater allows for increased flexibility of the mesh and promotes collagen deposition and ingrowth, the TVT mesh satisfies that criteria. There most well-accepted measurement for synthetic materials is the measurement of the widest pore, and is even referenced as the standard in the most recent Ford 2015 Cochrane Review. As noted in Moalli et al (2008), TVT had the largest pore size at 1,379 microns, which is equivalent to 1.379mm [82].

Table 1 Textile properties (including load at failure) provided by the manufacturers listed at the top (AMS, American Medical Systems) describing the different meshes tested in this study

Mesh type	Gynecare	Boston Scientific	AMS	Bard	Caldera	Mentor
Mesh thickness	0.63 mm	0.66 mm	0.66 mm	0.62 mm	0.48 mm	0.27 mm
Pore size	1379 μm	1182 μm	1000 μm	1160 μm	698 μm	374 μm
Fiber size (diameter)	0.15 mm	0.15 mm	0.15 mm	0.13 mm	0.15 mm	0.08 mm
Weight (g/m^2)	100	100	110	81	140	70
Relative porosity	53.9%	57.7%	52.1%	N/A	68.2%	N/A
Load at failure	70 N	70 N	65.6 N	60 N	70 N	76 N
Mesh edges/features	Tanged	Tanged/heat sealed midsection	Tanged/tensioning suture	Tanged	Not tanged	Not tanged; sealed edges

Coda (2012) more recently proposed a further classification for mesh groups; ultralight ≤35 g/m2, light 35–70 g/m2, standard 70–140 g/m2, and heavy ≥140 g/m2[83]. Even though this particular classification was not proposed until after the introduction of the TVT design, it meets the "ideal" requirements for use in SUI surgery. However, some authors have described this type of weight classification as meaningless because weight of the mesh depends on both the weight of the polymer (specific gravity) and the amount of material used.[84] They noted that different polymers have different specific gravities (PP=0.9 g/cm^3, PVDF=1.7 g/cm^3), and not all lightweight meshes are constructed with large pores.

Due to the specific microflora of the vagina we have learned that monofilament meshes perform better than tightly woven and/or multifilament materials. Gomelsky el al (2007) in an assessment of the biocompatibility of synthetic sling material concluded that "the most biocompatible material for sling construction is loosely woven or knitted, monofilament, macroporous, polypropylene"[85]. Additionally, polypropylene has been placed in hundreds of millions of people worldwide for nearly 50 years without evidence of it causing systemic disease including cancer[86]. The clinical benefits and safety profile of polypropylene being used as an implant, and specifically Prolene polypropylene sutures and mesh, have been demonstrated in the medical literature and have been well known for decades.

As a result, TVT mesh is a suitable and currently one of the most appropriate permanent mesh implants for the treatment of SUI. If placed in properly, pore size and integrity should remain and not collapse. Subsequently as the pores size remains above 1mm fibrotic bridging should not occur. Additionally, if placed correctly fraying, particle loss, curling and deformation should not occur. The 2016 AUGS and SUFU position statement endorsed by AAGL, ACOG, SGS, and others, refers to TVT as a "macroporous, monofilament, light weight polypropylene" mesh when describing the long-term durability, safety, and efficacy of midurethral slings"[87]. The findings reported in the position statements and medical literature are consistent with my clinical practice and experience with TVT and midurethral slings.

Petros (2015), as part of the Ulf Ulmsten Memorial Lecture 2014, discussed the early assessments the TVT prototypes, and the benefits of using Ethicon's Prolene mesh for the TVT: "Mersilene was easy to use, non-stretch, and effective, but it had a high erosion rate (14%). By 1996 polypropylene mesh tape had solved the problem of erosions and become universally accepted."[88] Ulmsten published on the TVT prototype IVS, using Mersilene, Teflon, and Lyodura in 1995, reporting 78% completely cured, 12 considerably improved, and 2 patients who reported pains and signs of sinus formation resulting in the removal of the Gore-Tex slings[89]. Falconer and Ulmsten (1996) reported an 84% completely cured rate and 5% considerably improved with IVS using Mersilene, but noted early rejection of the sling. They

previewed the great success with Prolene mesh used in TVT: "After extensive experimental and clinical research a new sling material that will possibly eliminate the rejection problem has been introduced, with very promising results"[90]. In a subsequent publication, Ulmsten (1996) discussed the improvements in finding no defect in healing or rejection with Prolene mesh compared to the 8-10% rejection rate with Gore-tex and Mersilene.[91] Ulmsten (2001) discussed the benefits and excellent clinical results with the Prolene mesh TVT in several early publications[92,93].

A standard weight mesh such as the TVT has been shown to have a better success than lighter weight meshes. Prien-Larsen (2016) recently published a prospective study comparing a 100 g/m^2 with low stiffness and rough edges (similar to TVT) to a lighter weight 60 g/m^2 mesh with high stiffness and smooth edges[94]. At 12 months there was a significant difference in objective cure rates favoring the heavier weight mesh 86% vs 96%.

Due to the large volume of data that existed on the safety and efficacy of mechanically cut TVT it was appropriate for Ethicon to not quickly modify/change the mesh to the laser cut mesh. As described by Moalli et al (2008) altering a mesh might change the characteristics[95] and this may affect way the mesh performs. One of theories is that the rough edges of the mesh were the most important property of the mesh holding the sling in place in the early postoperative days[96]. Therefore, it was appropriate for Ethicon to not introduce changes to the mesh too rapidly. Moreover, there is no reliable clinical data that has demonstrated a decrease in complications that are attributed to whether the mesh is mechanically cut or laser cut.

TVT, as do all other implants, induces an inflammatory response; however, polypropylene has a greater degree of biocompatibility than polyester or expanded polytetrafluoroethylene[97] that have previously been used for synthetic slings. Clinically, I have not seen this chronic inflammatory reaction to be of any significance. Additionally surgeons must use the prevailing material that is available at the present-day and currently for slings that material is polypropylene.

Furthermore, since an overwhelming majority of midurethral sling studies have used TVT mesh as a result it is considered the gold standard when comparing mesh and sling characteristics for the treatment of SUI.

TVT is reasonably safe and effective, as compared to the Burch and autologous fascial sling procedures, for its intended use of treating SUI.

Ward et al (2007) reported 5 year follow-up in an RCT of TVT vs Burch, overall cure rates were similar. Both groups had improvement in symptoms of urgency, frequency, urge and stress incontinence, and unexplained incontinence. De novo urgency and urge incontinence were also similar between the 2 groups occurring in 5 and 4% in the Burch group and 2% and 1% in the TVT group, respectively[98]. QOL as measured by the SF-36 improved and did not differ between the two groups. In 2002 Ward published 6 month data and showed a significant increase in operative time, hospital stay, and return to normal activity and work in the Burch group[99]. It is interesting to note that in the TVT group the median hospital stay was 1 day and return to work was 4 weeks. Today, a TVT procedure is performed on an outpatient basis, the procedure takes about 30 minutes in a teaching institution such as ours, and patients return to work in days as opposed to weeks.

Paraiso et al (2004) performed an RCT comparing TVT to laparoscopic Burch. At a mean of 20 months the objective cure rate for Burch was significantly lower at 81% vs 97% for TVT. Subjective cure rates were also higher for the TVT group. Operative time was significantly longer in the Burch group[100]. At long term follow up with a median of 65 months there was no statistically significant difference in subjective cure, reporting no urinary incontinence, 42% in the Burch and 58% in the TVT group[101]. However there was a tendency to report urinary incontinence at an earlier time in the Burch group than the TVT group suggesting better durability and longevity of the TVT.

The overall risk of reoperation for a complication with a TVT procedure is low. Welk et al (2015) in a 10 year review of 59,887 women who underwent sling procedures in Canada reported a 2.2% incidence of mesh removal or revision. The authors noted that high volume surgeons had lower rates of complications, and that complications were treated by the same surgeon who performed the initial surgery in 62.1% of cases. Over a 10 year time span approximately 1/30 women will have a reoperation for mesh revision or removal[102]. This finding corroborated previous findings reporting a 3.2% -3.7% reoperation rate for midurethral slings[103, 104]. Other authors have also demonstrated similar complication rates with midurethral slings.[105]

Novara et al (2008) performed a meta-analysis and systemic review comparing complication rates of midurethral slings to Burch and autologous slings. Other than bladder perforation TVT had similar complication rates to Burch in terms of pelvic hematoma, urinary tract infections, storage lower urinary tract symptoms, and voiding lower urinary tract symptoms. However, the reoperation rate was higher for the Burch procedure[106].

In a study by Moen et al (2009) comparing patients undergoing abdominal sacral colpopexy (ASC) repair with synthetic midurethral sling compared to those undergoing ASC with Burch, the synthetic sling group resulted in a significantly lower rate of post-operative incontinence symptoms[107].

Complications reported with fascial pubovaginal slings include voiding dysfunction, irritative voiding symptoms, cystotomy, postoperative infection, urethral erosion, and postoperative pain syndromes[8]. The most common complications from pubovaginal slings are voiding dysfunction and irritative voiding symptoms. Jarvis (1994) reported 12.8% mean incidence of postoperative voiding disorders after pubovaginal slings[108]. When comparing TVT to traditional slings complication rates with respect to de novo urgency and urge incontinence and sling revision are similar[109]. Zaragoza (2006) in a retrospective review with a mean follow up of 25 months reported a 5% rate of persistent incisional pain after a rectus fascial sling[110]. Blaivas et al (1998) in a retrospective study reported a 2% permanent urinary retention rate with a pubovaginal

fascial sling[111]. It is important to note that in my experience permanent urinary retention requiring life-long catheterization is an emotionally devastating complication to women.

McGuire et al (1978) reported complications after using a 12 cm long strip of rectus fascia slings, noting that problems with autologous fascial slings included "persistent postoperative urinary retention, injury to the bladder or urethra during the operation, erosion of the sling into the urethra or bladder as a late complication and difficulty in judging sling tension to ensure a satisfactory result"[112]. McGuire noted that the autologous fascial sling procedure has usually been reserved for patients who have had failures from previous operations.

Kaplan et al (1996) evaluated autologous fascial slings and reported an operative time of 84 minutes, mean hospitalization time of 3.7 days, catheterization time of 17.4 days, and 28 days lost from work[113]. The authors discussed how in 1996 they were counseling their patients about how vaginal wall slings may result in postoperative sexual problems in sexually active women and "routinely counsel patients on this potential problem".

Although mesh erosions and exposures are often referred to as a unique complication of synthetic midurethral slings, they can still occur, although less frequently, with autologous fascial slings and erosions of permanent sutures as described with the Burch procedure. Golomb et al (2001) reported on a case of traumatic erosion of the urethra by an autologous fascial sling that was managed by bilateral release of the sling tension[114]. They noted a review of the published literature at that time, reporting 5 cases of urethral erosions (0.003%) in 1,715 case reports of an autologous fascial sling, compared with 27 (0.02%) of 1,515 cases associated with synthetic materials. Petrou et al (1999) describe the urethrolysis procedure to treat voiding problems after sling procedure[115].

Blaivas (1994) noted that autologous slings never achieved widespread popularity, "mainly due to the perception that the procedure is technically more demanding than the standard urethropexy, and the complication rate, particularly in the hands of the inexperienced surgeon, is

reportedly higher. The most common and troublesome complications are injury to the bladder or urethra, urinary retention, and detrusor instability"[116].

Fokaefs et al (1997) reported autologous fascial sling shrinkage in length by 37% of the original length and shrinkage in width by 63% of the original width, in addition to a reduced tensile strength of 53%[117]. They suggested that "shrinkage of fascia in length must be taken into account in order to avoid overcorrection and urethral obstruction," and that reasons for shrinkage of fascia are most likely due to an impaired nutrition, denervation of the fascia, and loss of functional stress. The authors noted that reported complications of fascial slings include urinary retention requiring early sling revision, erosion of the sling into the urethra or bladder, pain at the site of attachment, and recurrence of SUI. By contrast, clinical studies have found no shrinkage or contraction after TVT in the short term (Dietz 2003[118]; Lo 2004[119]) through ultrasound or in the long-term (Nilsson 2013 17 year follow-up)[120]. Conversely, Sindhwani et al (2015) reported a 15.9% in vivo reduction in mesh area for PVDF (poly Vinylidene Fluoride) DynaMesh[121].

In a study by Padmanablhan (2016) comparing autologous rectus fascial slings vs synthetic midurethral slings, similar cure rates were noted for the two procedures, 78.2% for midurethral sling vs 71.9% for autologous sling. However, multivariate analysis showed midurethral sling patients were more than twice as likely to exhibit subjective improvement in UDI-6 and VAS scores than autologous sling patients[122].

Trabuco et al (2009), from the Mayo Clinic, reported similar results comparing a polypropylene midurethral sling to autologous slings. They "consistently observed higher incontinence rates with autologous fascia than with midurethral slings," and patients with autologous slings "had a higher rate of urethrolysis (13.9% vs 1.2%), reported lower satisfaction (78.5% vs 92.0%), and had higher rates of urge incontinence (38.0% vs 25.2%) than did patients who had a midurethral sling"[123].

Chronic pelvic pain and dyspareunia are also complications that can occur after any type of pelvic surgery. However, they are unfortunately also common in the general female population and the causes of either are multifactorial. It is estimated that chronic pelvic pain is present in 14.7% of women 18-50 years of age and more than half due to an unknown cause[124]. Dyspareunia is present in approximately 5-6% of premenopausal women ages 30-50[125]. Menopause, and vaginal atrophy that consequently occurs, is one of the main contributors to dyspareunia in postmenopausal women. Approximately, 21.5% to 29% of postmenopausal women experience dyspareunia[126]. A population based study reported prevalence of dysmenorrhea, dyspareunia, pelvic pain, and irritable bowel syndrome was 90%, 46%, 39%, and 12%, respectively[127].

Surgery is one of the most common causes of developing chronic pain. Chronic postsurgical pain is seen after cesarean section and hysterectomy. Two years after vaginal hysterectomy it persists in 2.2% of women and 6.7% after abdominal hysterectomy[128]. After cesarean section a recent review and meta-analysis has revealed an 11% rate of postoperative chronic pain one year after surgery[129]. A previous history of chronic pain has been shown to be a major risk factor for developing post-operative pain. Abdelmonem et al (2010) reported de novo dyspareunia rates as high as 5% de novo dyspareunia after total abdominal hysterectomy and 20% after vaginal hysterectomy[130].

Pelvic pain has long been known to be a common consequence of a Burch procedure. As reported in the 1990s persistent pelvic pain occurs in 12-27% of patients[131,132]. Post colposuspension syndrome, groin pain at the sites of the suspension sutures in a Burch procedure, has been described to occur in 12% of patients[133]. Galloway et al (1987) reported only 44% of patients being cured and complication-free at 4.5 year follow-up after an open Burch, with long-term complications including: persistent incontinence 16%, voiding difficulties 16%, urge syndrome 14%, post-colposuspension syndrome 12%, uterine prolapse 4%, enterocele 4%, dyspareunia 4%, and recurrent incontinence 2%. Demirci et al (2000) reported late complications after Burch colposuspension in 220 women, including: cystocele in 18, rectocele in 32, enterocele in 35, dyspareunia in 6, and groin or suprapubic pain in 15[134].

An open Burch procedure is performed through a Pfannenstiel incision. It has been well documented that a Pfannenstiel incision can be a cause of chronic pain. Nerve entrapment with a Pfannenstiel incision is not uncommon and occurs in 3.7% of patients[135]. Loos et al (2008) reported on women who had surgery with a Pfannenstiel incision. At a median of 26 months 33% experienced chronic pain at the incision site, 8.2% experienced pain on a regular or continuous basis, and 7% reported severe pain[136]. Liapis et al (2002) performed an RCT comparing Burch to TVT. The reported persistent pain at 6 months was 11% in the Burch group vs none in the TVT group[137].

Any type of vaginal surgery has long been known to have the potential of causing dyspareunia and this was documented and published over 50 years ago[138]. Vaginal hysterectomy, prolapse surgery, and episiotomy[139] have all been shown to cause dyspareunia. When a Burch procedure is combined with a posterior repair the postoperative dyspareunia rate may be as high as 38%[140].

Pubovaginal slings have also been known to cause dyspareunia. Schimpf et al (2014) in their meta-analysis of slings reported dyspareunia occurring in 1% of women receiving a pubovaginal sling as compared to 0% in the retropubic midurethral sling group[141].

Numerous studies on TVT have been shown to improve the sex lives of women. Ghezzi et al (2005) prospectively reported on TVT effects on overall sexual function. At a median of 12 months there were no changes in dyspareunia rates pre- and postoperatively[142]. Jha et al (2009) prospectively reported TVT effects on sexual function. At 3 months after surgery orgasm incontinence, penetration incontinence, post-coital infections, anxiety, and avoidance of sex were all reduced[143].

Unger et al (2015) performed a retrospective case control study reporting an overall 2.7% midurethral sling revision rate and a 0.2% rate for vaginal pain/dyspareunia[144]. Furthermore, all patients with pain complaints had partial or complete improvement after revision. The risk of a

major complication of bowel, vascular, nerve injury with a TVT procedure is low to rare, less than 1%[1], and likely in my opinion does not differ from the needle procedures performed in the 1990's. The incidence of severe complications with TVT is not common. Furthermore the majority of complications that occur with a TVT occur in the first year after implantation and are easily managed.

The midurethral sling has become the standard treatment for SUI, so much so that comparative studies against Burch and pubovaginal slings have largely been abandoned[145]. In 2011 midurethral slings were already considered the gold standard for primary surgical treatment of SUI[146]. The studies which are currently being performed today are to determine which midurethral synthetic slings have the highest cure rate, are most appropriate for particular patients, and have a lower complication profile.

The surgical risks and complications for stress incontinence procedures are commonly known and not unique to TVT. Mesh exposure or erosion is generally seen with synthetic slings, and has been well documented in the literature evaluating other synthetic sling materials for decades. Most vaginal exposures from a TVT do not require surgical treatment[107]. Although if necessary surgical correction for exposure is a relatively simple procedure performed on an outpatient basis. Erosion of mesh into the bladder is rare. Bladder and bowel perforation can occur and nerve entrapment has been reported in patients who underwent needle procedures[147]. Bladder perforation has also been seen in patients with Burch procedures. Rardin et al (2007) reported an 18.2% suture erosion rate at a median of 15 months follow-up after Burch, with 6 of the 12 patients requiring a surgical revision or excision of sutures[148].

Albo et al (2007) in an RCT of Burch vs autologous sling reported an operative time of 136-138 minutes, and at 24 months 10% and 13%, respectively, had serious adverse advents which included: ureteral injury, ureterovaginal fistula, incidental cystotomy, erosion of suture into bladder, pyelonephritis, pelvic pain, bleeding, and wound complication requiring surgical intervention. Serious adverse events were reported in 13% of patients with autologous sling and

10% with Burch. Adverse events were more common in the autologous sling group than in the Burch group (63% vs. 47%). Reoperation in the sling group to reduce voiding symptoms was 6.1% and the total reoperation rate was 10.1%[149]. In the Burch group the reoperation rate was 7.3% and included repeat surgery for failures and wound complications. Twenty patients in the autologous sling group experienced voiding dysfunction leading to surgical correction; 11 patients experienced wound complication requiring surgical intervention; and 2 patients complained of pelvic pain. In the Burch group, 13 patients had wound complications requiring surgical intervention and 1 patient had an erosion of suture into the bladder. When the same cohort of patients was followed up to 7 years, 26% of patients in the Burch group opted for repeat surgical treatment for recurrent SUI[150]. The authors noted that objective cure rates decreased during a period of 2 to 7 years postoperatively from 42% to 13% in the Burch group and from 52% to 27% in the autologous sling group.

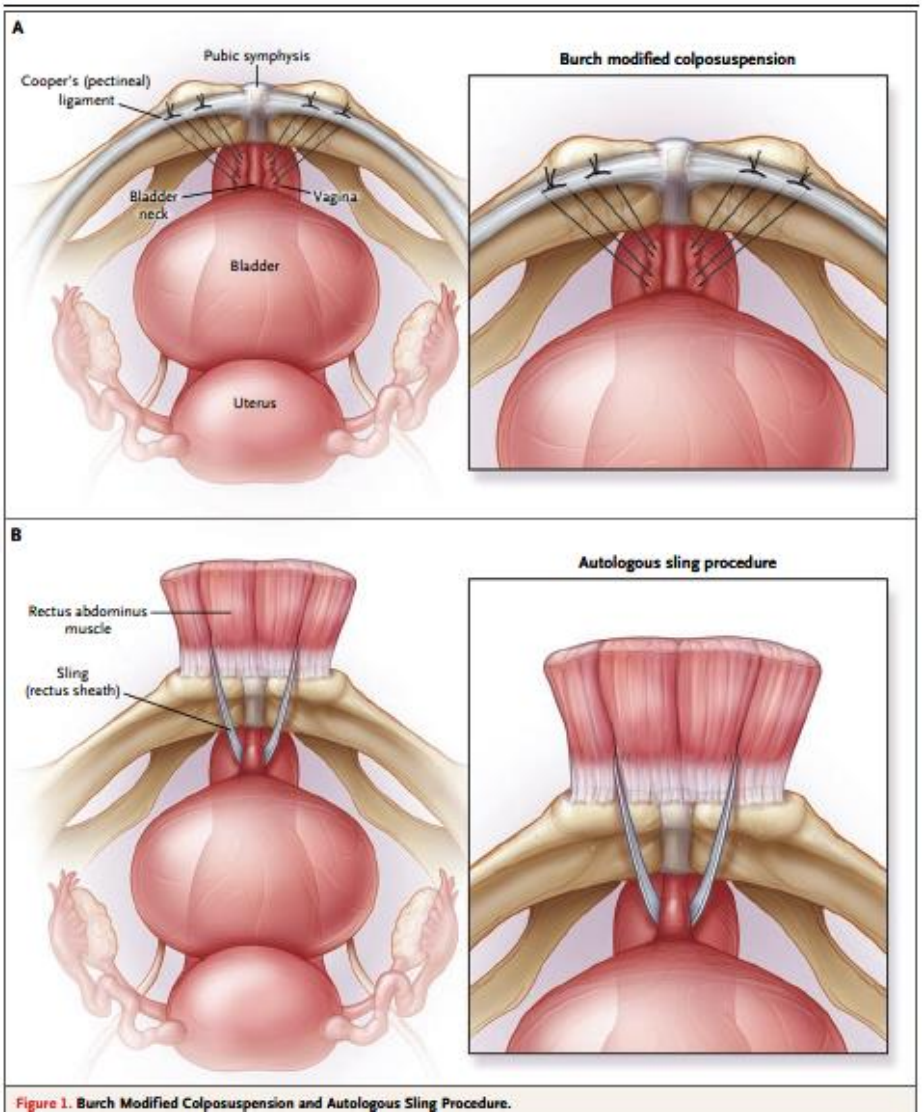

Figure 1. Burch Modified Colposuspension and Autologous Sling Procedure.

A Cochrane review in 2011 reported that traditional slings had a higher rate of voiding dysfunction than midurethral slings, and a higher reoperation rate for sling release 9% vs 2%[151]. The review concluded that midurethral slings seem to be as effective as traditional slings, but midurethral slings had a lower rate of adverse events.

The surgical risks of synthetic slings were well documented in the literature prior to the introduction of the TVT. In Leach's (1997) meta-analysis for the American Urological Association (AUA) complications described from synthetic slings included: vaginal and urethral

erosion, fistula, wound sinus, wound infection and seroma[26]. All of these complications were also seen in patients who had an autologous sling.

Surgeons are exposed to the risks and complications, resulting from surgical procedures for stress urinary incontinence, in their training and are expected to continuously learn and preserve a high level of knowledge and judgment thorough their careers. This process begins as a medical student, is enhanced during residency and fellowship, and maintained and reinforced as a practicing physician.

The AUA National Medical Student Curriculum states: "Synthetic mid urethral slings are ideal for the patient with anatomic stress incontinence who is looking for a surgery with minimal recovery time. In randomized surgical trials for stress incontinence the TVT mid urethral sling has been shown to be comparable to a Burch colposuspension which is a retropubic suspension at 6, 12 and 24 months. Due to concerns of bladder, bowel or major vessel injury slings have been developed that are placed transversely underneath the mid urethra from one obturator foramina to the other. The advantage of this sling is that the retropubic space is avoided. These slings do have more groin issues with pain and or numbness at the site of the sling at the top of the leg. Infection, although exceedingly rare, may result in necrotizing fasciitis. A randomized surgical trial by the NIH comparing a TVT mid urethral sling to two different obturator slings, Monarc and TVT-O, showed that no procedure is superior to the other"[152].

The fundamental components of the risks and benefits of surgical treatment for stress urinary incontinence are taught and expected to be learned during residency. The AUGS urogynecology resident objectives states, "Know the various approaches, both nonsurgical and surgical, for the treatment of urodynamic stress incontinence. Understand the difference between traditional and minimally invasive surgical approaches, eg open Burch versus laparoscopic Burch, and traditional pubovaginal sling versus mid-urethral sling. Understand and perform an open retropubic suspension. Understand the various laparoscopic approaches to retropubic urethropexy. Understand and perform the Tanagho modification. Understand the difference

between a pubovaginal and mid-urethral sling. Understand and perform a mid-urethral sling, using either a retropubic or trans-obturator approach. Understand the benefits, risks, and how to decide on a vaginal versus abdominal versus combined surgical procedures for the correction of urodynamic stress incontinence. Understand the high-risk factors for failure of anti-incontinence procedures. Understand the relative indications for urethropexy versus sling versus urethral bulking agents. [The resident should be] able to discuss risks, benefits, and expected outcomes of nonsurgical and surgical management of SUI"[153].

Additional knowledge is gained during fellowship in Female Pelvic Medicine and Reconstructive Surgery. The 2012 ABOG and ABU Guidelines to Learning in FPMRS [154]states: "B. Surgical Treatment. 1. Perform a variety of evidence-based surgical procedures for stress incontinence…. Perform and describe the indications, intra and postoperative complications, and success of the following continence procedures… Sling procedures… Fascial (fascia lata, rectus fascia), Synthetic (1) retropubic, (2) Transobturator." Also, page 8, section 7 describes: "Identify, evaluate, and manage complications associated with continence surgery, including… foreign body associated complications…" Fellows are also expected to learn about mesh properties and clinical results with synthetic midurethral sling procedures such as TVT: "Augmenting Surgical Materials. 1. Discuss different types of graft materials using in prolapse and incontinence surgery, including graft properties, advantages, and risks associated with each graft… 2. Discuss relevant characteristics (pore size, filament type, flexibility, tensile strength) of augmenting surgical materials. 3. Discuss the level of evidence (success and complications) for the use of augmenting surgical materials prolapse and incontinence surgery."

In January of 2013, retroactive to July 2012, the ACGME assumed the authority of certifying fellowship programs in in FPMRS. The Program Requirements for Graduate Medical Education in FPMRS states: "Fellows must be able to competently perform all medical, diagnostic, and surgical procedures considered essential for the area of practice. Fellows must demonstrate competence in: … performing surgery for urinary incontinence including native tissue and synthetic slings…" Also, "Completing the F3 year must demonstrate competence in their knowledge of… indications, contraindications, limitations, complications, techniques...for…

urinary incontinence"[155]. These requirements are met through didactic sessions, required readings, journal clubs, morbidity and mortality conferences and one on one teaching with attending surgeons. As the program director of the fellowship program in FPMRS at Northwell Health I am accountable and responsible for these program requirements being met.

Practicing attending surgeons are expected to maintain and further their knowledge by reading and staying current on the medical literature, by attending medical conferences or through continuing medical education courses. Surgeons who are certified by ABOG or AUA are required to meet maintenance of certification requirements (MOC). A component of the ABOG MOC requirements include reading peer reviewed journal articles and answering quiz questions regarding the articles.

Surgical risks and complications are inherent to surgery itself, commonly known and unfortunately expected. Patients themselves intuitively are aware that there are risks to surgery. Surgeons strive in their everyday practice to reduce risk and widen the benefit to risk profile for each patient. The recent boom in technology, through information exchange and data mining has increased our ability to expose and quantify short and long term complications, on a regional and national basis, and to further enhance our knowledge and understanding. However, these risks and complications are truly not enlightening data to surgeons who are well aware of surgical risk through their training and practice. Rather, the increased information enhances our knowledge in order to provide the highest quality of care.

The TVT IFU appropriately warns surgeons of the potential adverse reactions that are specific to the device including damage to vessels, nerves, bladder, urethra, or bowel as well as the possibility of extrusion, erosion, fistula formation or inflammation. There is no overt need to describe the possibility of chronic pelvic pain, or dyspareunia, because as stated previously, these are inherent risks to surgery, and vaginal surgery in particular, which are commonly known.

Furthermore, as part of the training in Obstetrics and Gynecology, Urology, and Female Pelvic Medicine & Reconstructive Surgery sexual health and dysfunction and its causes, which include surgery, are required teaching. Obstetrics and gynecology residents are trained to care for patients on sexual health[156]. The ACGME Program Requirements for Graduate Medical Education in FPMRS states, on page 14 in article IV.A.5.b).(2).(b) fellows "completing the F2 year must demonstrate competence in their knowledge of clinically pertinent areas of …., sexual dysfunction, and psychosocial aspects of pelvic floor disorders"[114]. The ACGME Program Requirements for Graduate Medical Education Urology states, on page 15 in article IV.A.5.b).(1) that residents must gain knowledge in female pelvic medicine and sexual dysfunction[157].

The risks of synthetics slings were documented in the literature before the introduction of the TVT sling[158]. The risk of dyspareunia and effects on sexual function with a vaginal synthetic mesh placement were also well known and documented in the gynecology and urology literature in the late 1990's. The possibility of developing vaginal pain from a sling was well publicized and known in January of 1999, shortly after TVT was introduced, when a woven polyester sling was recalled and removed from the market. Vaginal pain as a consequence of this polyester sling was published in December of 1999[159].

The possibility of developing chronic pain and dyspareunia are inherent to vaginal surgery independently, and do not need to be explicitly mentioned in an IFU as every implanting surgeon would have possessed this knowledge through their education, training, and practice. Subsequently, surgeons are aware of the consequences of chronic pain and dyspareunia developing after any incontinence procedure, including a sling procedure using TVT.

Surgeons use the IFU of a product as guide and not as Holy Scripture. For instance, the IFU states that "adjust the implant so that leakage is reduced, allowing only a few drops of urinary leakage to occur under stress". I perform slings under general anesthesia, as do most of my colleagues, and we do not perform a stress test at the time of implantation. Additionally, a contraindication in the IFU includes women with plans of future pregnancy. I myself have implanted slings in women knowing they desire future childbearing and this has been reported in

the literature as well[160]. Just as surgeons do not rely unconditionally on the IFU instructing them how and who to do the procedure on, they also do not rely on it solely for adverse reactions. Surgeons are also not expected to rely on a manufacturer to teach us how to manage complications. Surgeons must be fundamentally aware of surgical adverse reactions and complications, as there are many procedures that we currently perform that do not have an IFU and we still must convey the risks to our patients.

There are no clinical difference, complications, or safety concerns that I have seen or am aware of with TVT (mechanically cut) as compared to TVT-Exact (laser cut).

I was an early adopter of TVT, which has been available in mechanically cut in the United States from 1998 to present, and also used TVT laser cut mesh, in addition to TVT-Exact (only available in laser cut), and have not seen any noticeable difference in objective cure, subjective cure, or complications, including mesh exposures, pelvic pain, and dyspareunia. I have searched the literature and have not identified any reliable clinical studies that have demonstrated a causal link between the edges of the mesh and complications. I have seen reports and testimony from experts, including Dr. Bruce Rosenzweig, suggesting that both mechanically cut TVT and laser cut TVT are defective because they both lead to the same potential complications, although by different mechanisms (stiffer mesh with laser cut and particle loss/fraying with mechanically cut). These opinions are not based on reliable scientific data. Thubert et al (2016) retrospectively reviewed TVT vs TVT-Exact and at 12 months subjective and objective success rates were similar as were peri- and postoperative complications[161]. Both TVT and TVT-Exact resulted in 0% mesh exposures.

Lim et al (2010) reported compared 556 TVT slings (mechanically cut) to 108 Advantage slings (4.5 cm heat-sealed portion under the midurethra portion) between 1997 to 2007, and found no difference in subjective cure rates (83.3% for Advantage and 85.3% for TVT), and no differences in complications such as mesh exposure, pain, or dyspareunia[162]. There appeared to be a trend to more de novo urgency and voiding difficulty in the Advantage group compared to the TVT group, but it is conjecture to suggest that this is due to the differences in the edges of the mesh. Plaintiffs experts postulate (in laser cut cases) that “stiffer” laser cut meshes cause an

increase in mesh erosions/exposures, but their conjecture is not supported by studies, such as Lim (2010), finding no statistical difference in mesh erosions/exposures for TVT mechanically cut and heat-sealed Advantage sling (0% mesh erosion/exposure). As noted by the authors, but apparently disregarded by plaintiffs' experts who lack any reliable data to support their opinions on the clinical differences between mechanically cut and laser cut, "However, only larger studies would determine whether the stiffer, heat-treated, and detanged portion Advantage sling would differ from TVT with regards to erosion complications."

Variables	ALL, n=664	TVT, n=556	Advantage sling, n=108	p value
Experienced surgeon (%)	82.1	81.7	84.3	0.58
Anesthesia mode (%)				
Local	44.6	44.1	47.2	
Regional	14.6	16.1	5.6	0.01
General	40.8	39.6	47.2	
Bladder injury (%)	3.2	2.9	4.6	0.36
Concomitant prolapse surgery (%)	38.0	37.9	38.0	0.99
Admission days	1.79	1.85	1.52	0.12
Follow-up (weeks)	215	235	111	<0.001
Subjective success (%)	84.9	85.3	83.3	0.66
De novo urgency (%)	16.0	14.7	22.2	0.06
De novo urge incontinence (%)	7.7	7.4	9.3	0.55
De novo voiding dysfunction (%)	7.4	6.7	11.1	0.11
Sling erosion (%)	1.3	1.43	0	0.37
Sling division (%)	1.5	1.1	3.7	0.17
Recommend to friend (%)	93.1	93.2	92.6	0.84

Agawala (2010) compared TVT to Lynx (heat-sealed) and found no differences in vaginal mesh exposures, surgical interventions, subjective cure, objective cure, patient satisfaction, failure, postoperative UTI, or new onset of detrusor instability.[163] The authors postulated that the difference in postoperative voiding dysfunction (21% with TVT and 15% with Lynx) could be due to the midurethral seal; however, the authors also speculated that the heat-sealed tape of the Lynx could explain the increased rate of vaginal graft exposure with the Lynx.

Table 2. Complications and results

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Complications and results	TVT group (n=48)	Lynx group (n=48)	P
Trocar injury	2 (4%)	3 (6%)	.21
Hemorrhage	0 (0%	0 (0%)	
Bowel Injury	0 (0%)	0 (0%)	
Postoperative voiding dysfunction (retention/ hesitancy/poor stream)	10 (21%)	7 (15%)	<0.001
12-14 days of catheterization	2 (4%)	2 (4%)	.08
Postoperative UTI	5 (10%)	6 (13%)	.12
Interventions			
Removal of sling	0 (0%)	1 (2%)	.43
Sling slit	1 (2%)	0 (0%)	.58
Vaginal sling exposure	0 (0%)	2(4%)	.45
Subjective cure	45 (94%)	44 (92%)	.08
Objective cure	46 (95.8%)	45 (93.8%)	.07
Patient satisfaction	44 (92%)	44(92%)	.12
Failure	3 (6%)	4 (8%)	.25
New onset detrusor instability	1 (2%)	1 (2%)	.99

Neuman (2011) suggested that the stiffer TVT-Secur (laser cut) might have caused the de novo dyspareunia in 5 of 77 patients (7.9%), compared to 0% in the mechanically cut TVT-O group.[164] Cure rates and postoperative voiding problems, UTIs, and mesh exposure/protrusion rates were similar between the two groups.

Table 3

Intraoperative and early postoperative complication rates[a]

Variable	TVT-Obturator group (n = 73)	TVT-SECUR group (n = 79)	p Value
Bladder, bowel, or urethral injury	0	0	NA
Operative blood loss >100 mL	0	1 (0.0)	4.80
Vaginal mesh protrusion	1 (1.4)	0	1.00
Operative field infection	0	0	NA
Early voiding difficulty	4 (5.4)	9 (11.7)	.15
Postoperative UTI	1 (1.4)	1 (1.3)	.99

NA = not available; UTI = urinary tract infection.
[a] Values are given as No. of patients (%).

Ethicon's benchtop testing showed no statistical difference in particle loss at 50% elongation when comparing TVT mechanically cut to TVT laser cut[165]. I have seen the Ethicon PowerPoint relied upon by plaintiffs' experts comparing the physical differences in TVT mechanically cut and TVT laser cut when stretched beyond the physiological range at 50% elongation. This type of destructive testing is not indicative of clinical use and does not translate into any clinical difference when properly used.

EXECUTIVE SUMMARY

Testing was conducted as part of design verification to evaluate the amount of particle loss at 50% elongation of Laser Cut TVT PROLENE mesh and Mechanical Cut TVT PROLENE mesh. The two sample sets were not found to be statistically different, however the average percent particle loss for Mechanically Cut TVT PROLENE Mesh is higher than that of Laser Cut TVT. The design verification results of this study meet the criteria for success as set forth in protocol and the TVT LCM design requirements matrix. The results of this study are listed in Table 1.

Table 1. Summary of Data

	% Weight Loss	
	LCM	MCM
Average	0.0047	0.0064
St. Dev	0.0059	0.0036

PVDF has not been shown to be a safer alternative design when used as a synthetic midurethral sling. The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR 2015 Report) found that there was "insufficient evidence on the performance, risk, and efficacy"

of other materials like PVDF, and that clinical experience with PVDF used in hernia surgeries "does not allow any reliable conclusions for use in urogynecological surgery." The SCENIHR Report concluded that studies so far using PVDF "do not provide sufficient clinical evidence on the urogynecological use of meshes made of this material, in particular concerning long-term performance"[166]. This is consistent with Kink et al (2011) reporting on the use of PVDF in rats, noting that "little is known about the long-term cellular reactions after more than three months"[167]. Padilla et al (2013) reported that TVT was a macro-porous mesh and had a successful cure rate of 82.4% and the tape could be adjusted without deformation, while Dynamesh (PVDF) had a success rate less than 80% and was "not malleable and could not be adjusted after implantation," which resulted in the PVDF meshes being "less well tolerated and presented a greater rate of urinary retention"[168]. Padilla discussed how meshes with elasticity, such as TVT, might be responsible for decreasing the likelihood of mesh exposure and urinary retention. PVDF has been described to have a "high rate of complications" when used for hernia repair, noting that "[e]ight patients experienced significant discomfort or pain as a consequence of laparoscopic ventral hernia repair that caused a change in their life situation making it necessary to change from normal work to pension or a recovery job," including 4 recurrences, three infections and one with disabling pain"[169]. PVDF demonstrated a severe foreign body reaction. Sommer et al (2013) reported a 6% risk of mesh-related reoperation and chronic pain in 19% of patients after PVDF Dynamesh laparoscopic ventral hernia repair.[170] The weight and pore size of PVDF[171] are not significantly lighter or larger than the weight of TVT (Moalli 2008). Endo et al (2016) reported a 21% decrease in surface area in rabbits with DynaMesh (PVDF), Ultrapro, and Marlex, with no differences in histological or biomechanical properties at day 90. Conze et al (2008) described PVDF as a heavy, large pore mesh.[172]

Mesh	Polivinylidene fluoride (PVDF)
Commercial product	DynaMesh PR4
Thickness (mm)	0.70
Weight (g/m^2)	73.0
Pore size (mm^2)	1.00–1.40
Biaxial tensiometry of implants	
Stiffness (comfort; N/mm)	1.04±0.29*

Mesh type	Gynecare
Mesh thickness	0.63 mm
Pore size	1379 µm
Fiber size (diameter)	0.15 mm
Weight (g/m^2)	100
Relative porosity	53.9%
Load at failure	70 N
Mesh edges/features	Tanged

The inflammatory reaction with the Prolene mesh used in TVT has been shown to be mild to minimal when compared to other synthetic materials, such as Mersilene. Falconer et al (2001) performed a 2 year biopsy study comparing Prolene (TVT) to Mersilene and found: "[a] minimal inflammatory reaction without a significant change in collagen solubility was observed in the Prolene group. In the control group no inflammatory reaction was seen. Mersilene gave rise to a significant foreign-body reaction in the paraurethral connective tissue after surgery. Such a reaction was not found with Prolene." They further noted that "there was a significant inflammatory reaction induced by the Mersilene mesh compared to the minimal reaction induced

by the Prolene tape." This is consistent with the pre-clinical tests conducted by Ethicon noting a minimal to mild inflammatory reaction.[173] These results are consistent with the statement in the TVT IFU that "Animal studies show that implantation of Prolene Mesh elicits a minimally inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue." Similarly, the statement describing animal studies also notes that "[t]he material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes." This statement accurately describes the results of the Miller (1967) study, and has been included in the Prolene suture NDA (New Drug Application) approvals for decades[174].

A chronic inflammatory response does not equate to chronic pain. Hill et al (2015) concluded that "[m]idurethral sling mesh excised for voiding dysfunction demonstrates elevated levels of inflammation compared to mesh that is excised for pain and/or exposure," and that "[t]he vaginal tissue fibrosis and giant cell reaction are similar in patients who undergo mesh excision for voiding dysfunction and pain, and/or mesh exposure"[175]. Klosterhalfen et al (2002) concluded that long-term incorporated polypropylene mesh in humans has a more favorable tissue response with increasing implantation interval and complications after 5 years were rare[176]. Notably, they found that "it was striking that there was little difference in inflammatory response in mesh removed for recurrence or chronic pain, contradicting the possibility of a specific tissue reaction as an underlying cause for either complication."

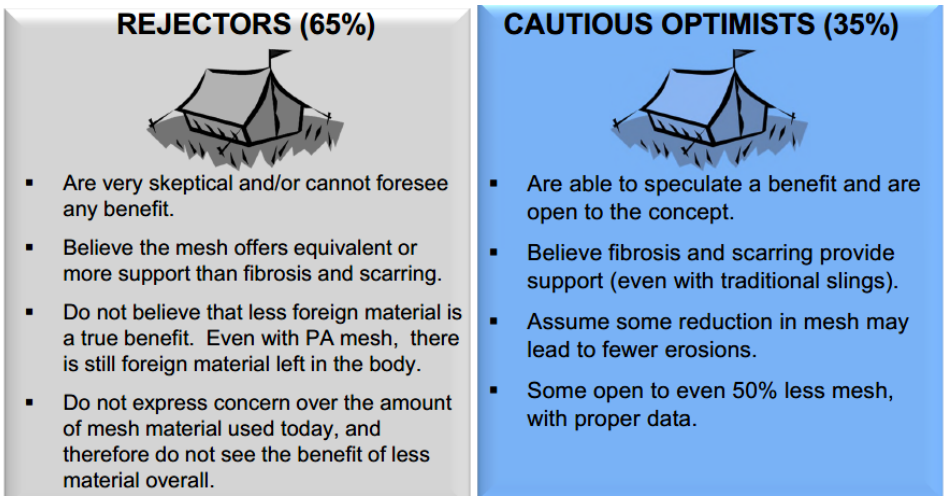
TVT mesh does not degrade in vivo. Studies suggesting that degradation occurs have not demonstrated any link to complications and alleged degradation, and any suggestion that alleged degradation causes complications is not based on any reliable scientific data. In fact, Thames et al (2016) confirmed that Ethicon's Prolene TVT does not degrade in vivo, and explains the "cracks" that were previously observed under SEM in some studies.[177] The authors concluded: "Our effective cleaning of explanted Prolene meshes and subsequent analyses showed that they did not degrade in vivo, confirming the in vivo stability of properly formulated polypropylene. Instead, the cracked layer that some researchers have identified as degraded Prolene is an

adsorbed protein–formaldehyde coating, resulting from the well-established formalin–protein fixation process, which occurs immediately upon placing an explant in formalin."

There is no reliable evidence that suggests Material Safety Data Sheets (MSDS) are clinically relevant or that polypropylene midurethral slings, such as TVT, cause cancer[178]. Moalli (2014) describes the problems with trying to extrapolate MSDS statements from raw materials noting that there is little relevance of MSDS documents to polypropylene mesh implants. Moalli concluded: "As we learned from the silicone breast implant controversy several decades ago, publications derived from a skewed interpretation of the literature and not solid evidence based on scientific data can lead to baseless damaging media hype and unscrupulous jury awards. It would be a tragedy for women worldwide if non-scientifically based articles regarding the potential hazards of polypropylene incited a spiraling course for the best (highest success rate and minimal morbidity) surgical procedure developed to date for stress urinary incontinence simply because of liability concerns by doctors, hospitals, and manufacturers. As treating physicians, we must let science and clinical studies determine our practice. More importantly, we must align with the millions of women who have been successfully treated with mesh with absolutely no evidence of systemic complications (including cancer) and who have regained control of their quality of life."

There is no reliable clinical evidence demonstrating that a larger pore, lighter weight mesh would be as efficacious or better and result in fewer complications than the 1cm wide strip of Prolene mesh used in the TVT. Even the Okulu (2013) study that plaintiffs' experts rely on had a 2% rate of mesh exposure, which is consistent with the rate of mesh exposure for TVT. Additionally, the Okulu study did not compare Ultrapro mesh to TVT, and was not performed as a pubovaginal sling with fixation and was not performed in the same manner as a tension-free sling midurethral sling. The clinical results of this one study have not been demonstrated in the long-term and have not been verified by other clinical studies or any RCT comparing Ultrapro to Prolene TVT. Further, Ethicon conducted cadaver studies to evaluate a lighter weight, larger pore, partially absorbable mesh to be used as a sling and it failed the cadaver studies because the mesh was too stretchy[179]. Ethicon conducted a study and found that approximately two-thirds of surgeons saw no potential benefit to introducing a lighter weight, larger pore, partially absorbable mesh, and

the remaining one-third was cautiously optimistic[180]. The FDA also rejected Ethicon's 510(k) application for this partially absorbable mesh (TOPA)[181].



TVT is appropriately designed for the treatment of SUI. The Prolene mesh used in TVT satisfies the prevailing criteria, as it is an Amid type 1, macroporous, monofilament, lightweight, polypropylene mesh. There is no compelling clinical literature that has demonstrated that a lighter weight, larger pore, laser cut, partially absorbable mesh, or a sling made from another polymer or biologic material, would be as safe and efficacious as TVT.

TVT is the best-studied incontinence procedure

The most extensively studied surgical treatment for stress urinary incontinence is the midurethral sling, and an overwhelmingly majority includes the TVT procedure. When evaluating the studies it is important to differentiate between the quality and hierarchy of what is likely the best evidence to support our treatment options and procedures performed. Systemic reviews of randomized controlled trials (level 1) provide the most reliable data followed by individualized randomized trials (level 2). Cohort studies (level 3) provide lower quality of evidence and finally case series provide the lowest (level 4)[182]. When available, treatments options should be based on level one and two evidence and not on level four. Numerous long term studies including RCTs, meta-analyses and systemic reviews exist to support the safety and efficacy of the TVT procedure. Several of these studies have already been mentioned in this report.

Novara et al (2010) performed a meta-analysis on midurethral slings as compared to Burch and pubovaginal slings. Patients who underwent a retropubic sling had higher continence rates as opposed to those who had a Burch procedure. Other than bladder perforation complication rates were similar as was subjective cure. When comparing midurethral slings to pubovaginal slings, there was no difference in overall or subjective cure rates. The prevalence of voiding lower urinary tract symptoms was also similar between the two groups but midurethral slings had a lower rate of storage lower urinary tract symptoms and reoperation rate[183].

Numerous studies exist with 10 or more years of outcome data on the TVT procedure. Heinonen et al (2011) reported a 90% objective and 78% subjective cure at a mean of 10.5 years post-operatively[184]. Svenningsen et al (2013) reported an 89.9% objective and 76.1% subjective cure rate at a median of 10.8 after surgery. Additionally, 82.6 % of the patients stated they were "very satisfied" with their surgery and only 2.3 % underwent repeat SUI surgery[185]. Nilsson et al (2013) prospectively followed TVT patients and reported results at a mean of 16.8 years. Objective cure was 91.3% and 87% of women were subjectively cured or significantly improved. One (2%) woman whose last follow up was year 7 to the study had an asymptomatic mesh exposure and one woman had a repeat midurethral sling placed, 15 years after the TVT procedure[120]. Aigmueller et al (2011) reported on women who had a TVT at a mean follow-up of 9.6 years. Objectively 84% were cured and 90% were subjectively cured or improved. Four (3.4%) patients had a repeat anti-incontinence procedure and the total reoperation rate including complications and failures was 7.8%[186].

Cox et al (2013) performed a review on the surgical management of female stress urinary incontinence. They concluded that midurethral slings are just as effective as, pubovaginal slings and the Burch procedure but with less associated morbidity. They go further to say that although Burch and pubovaginal slings are suitable treatment options for some patients “midurethral slings have become the new gold standard first-line surgical treatment”[187]

Schimpf et al (2014) performed a meta-analysis and review of RCT's with at least 12 month follow-up comparing midurethral sling procedures to Burch Urethropexy or traditional pubovaginal sling[103]. Subjective cure outcomes of TVT vs pubovaginal slings favored TVT slings. Retropubic slings had less blood loss, transfusions, wound infection, retention, OAB symptoms, shorter operating time, and hospital stay. Comparing midurethral slings to Burch there was no difference in objective or subjective cure, quality of life or sexual function outcomes. With respect to complications midurethral slings seemed to have a lower rate of short term complications as compared to Burch. Not surprisingly, retropubic slings appeared to have a higher rate of long term return to the operating room for retention or erosion, and OAB symptoms. However their study did not consider patients who returned to the operating for prolapse which occurs in 13.6 of patients who undergo a Burch procedure[20].

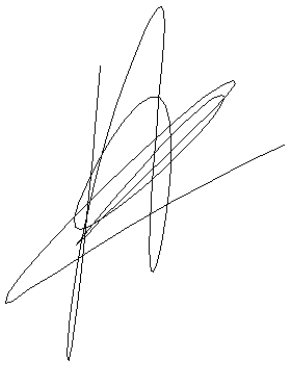
A recent Cochrane review by Ford in 2015 concluded "mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term. This review illustrates their positive impact on improving the quality of life in women with SUI"[1].

Allegations of Dr. Ulmsten's potential for financial bias is not a concern for me, nor should it be to implanting physicians and patients who receive the sling, given the corroboration of hundreds of independent studies from surgeons across the world.

Furthermore as a testament to the safety and efficacy, as well as the benefit to women in the US and worldwide every major medical society including: AUGS, SUFU, ACOG, IUGA, SGS, AAGL, AUA, NICE, EAU continue to endorse and advocate for the use of the midurethral sling, including the TVT, as the gold standard for first-line treatment option for uncomplicated SUI. Additionally, The FDA is not requiring any further studies for the TVT sling to support its use or safety[188].

Despite the overwhelmingly positive endorsements from medical societies and physicians, over the last several years after a steady decline in the number of autologous fascial slings placed, there has been a slight uptick in the number performed as a primary surgical procedure for stress urinary incontinence. In my experience, the reasoning for such is not based on scientific data and evidence based medicine, but rather on patient selection in absolutely refusing the placement of a synthetic midurethral sling, mostly due to inadequate and misinformation. A small minority of surgeons, in order to meet this demand, have reverted back to performing autologous fascial slings.

As a result of the success of the TVT as fully set forth in this report, the TVT will continue to improve the lives of women. The midurethral sling is currently the gold standard primary surgical treatment for SUI in women. I personally have implanted midurethral slings, including mechanically cut and laser cut TVT, into thousands of patients of which many are colleagues, physicians and their wives, and friends. I am proud to be able to offer midurethral slings to the benefit of my patients and will continue to do so.



Signed: _____

Harvey Winkler, MD

Date: February 5, 2017

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